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Nos. 95-754, 95-886

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES, COUNCIL OF STATE GOVERNMENTS, NATIONAL ASSOCIATION OF COUNTIES, NATIONAL LEAGUE OF CITIES, INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION, AND U.S. CONFERENCE OF MAYORS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS/CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

D. BRUCE LA PIERRE
WASHINGTON UNIVERSITY
SCHOOL OF LAW
One Brookings Drive
St. Louis, MO 63130
(314) 935-6477

RICHARD RUDA *
Chief Counsel
LEE FENNELL
STATE AND LOCAL LEGAL CENTER
444 North Capitol Street, N.W.
Suite 345
Washington, D.C. 20001
(202) 434-4850

* *Counsel of Record for the* Amici Curiae

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 preempt state tort law claims for injuries caused by a defective medical device.

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INTEREST OF THE *AMICI CURIAE*

Amici, organizations whose members include state, county, and municipal governments and officials throughout the United States, have a compelling interest in legal issues that affect state and local gov-

ernments. This case presents a recurring question that lies at the core of *amici*'s interests: the relationship between a federal statute and state tort law.

The States, through the mechanism of tort liability, have long protected their citizens by requiring that manufacturers compensate those injured by products as a result of defective design, manufacture, or labeling. The availability of state remedies is of obvious importance to persons injured by defective medical devices. In enacting the Medical Device Amendments of 1976 (MDA), Congress intended to enhance consumer protection, not to undermine it. Accordingly, it adopted a narrow preemption provision that it intended to be interpreted in a manner consistent with the MDA's overriding purpose of protecting consumers.

Medtronic's interpretation of the MDA's preemption provision would turn congressional intent on its head by stripping away the protection that state law affords consumers of medical devices, even in areas where no federal safeguards exist. Such an interpretation would leave consumers with far less protection than they had prior to the MDA's enactment. Moreover, it is wholly at odds with the FDA's longstanding regulatory pronouncements and principles of federalism.

Because of the importance of these issues to *amici* and their members, *amici* submit this brief to assist the Court in its resolution of the case.[1]

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[1] The parties have consented to the filing of this brief *amicus curiae*. Letters indicating their consent have been filed with the Clerk of the Court.

SUMMARY OF ARGUMENT

1. Manufacturers of medical devices are subject to liability under state tort law unless Congress had " 'the clear and manifest purpose' " to supersede the States' " 'historic police powers' " to protect the health and safety of their citizens. *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S.Ct. 1671, 1676 (1995) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

Congress did not state clearly in the Medical Device Amendments (MDA) any intention to preempt state tort remedies for consumers injured by medical devices, and " 'unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance.' " *United States v. Lopez*, 115 S.Ct. 1624, 1631 (1995) (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)); *see also Gregory v. Ashcroft*, 501 U.S. 452, 460-64 (1991). This requirement that Congress state clearly its intention to expand national power at the expense of the States is a critical means of protecting the States' role in our federal system of government. *See id.* Medtronic's argument that the MDA totally supplants state common law remedies is flatly inconsistent with the requirement that Congress state clearly such a fundamental reordering of state and national power.

In section 360k(a) Congress prohibited any state "requirement" for a medical device "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device . . . ." 21 U.S.C.

§ 360k(a). There is simply no evidence that Congress intended a state "requirement" to include state common law tort actions. Quite to the contrary, the sparse legislative history suggests that in section 360k(a) Congress was concerned only with the appropriate accommodation of state statutes and regulations with the MDA and not with state common law. *See* 42 Fed. Reg. 30,383 (June 14, 1977). Extrapolating this general language to preempt state common law tort actions violates the presumption against preemption and would absolve Congress from the responsibility to decide openly to leave consumers without any remedy for injuries caused by defective medical devices.

Even if the MDA could be interpreted expansively to provide for preemption of some aspects of state common law, the Lohrs' common law claims are not preempted. Congress, of course, never addressed the precise question whether particular common law claims were preempted or the extent of preemption because it did not intend to preempt state common law. In these circumstances, the FDA's longstanding interpretation of the preemptive effect of the MDA, as reflected in its existing regulatory pronouncements, is reasonable and entitled to deference. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984).

The FDA correctly turned to the structure and purpose of the MDA to determine the scope of preemption of state law. *See Travelers*, 115 S.Ct. at 1679-80. The FDA found that Congress' purpose of protecting consumers from unsafe and ineffective medical devices would be defeated if state law was preempted before the agency issued "compensating" regulations under the MDA. 43 Fed. Reg. 18,661, 18,663 (May 2, 1978). In interpreting section 360k

(a), the FDA correctly recognized that the promulgation of "specific" federal law "requirements" under the MDA is the prerequisite for preemption of state law. 21 C.F.R. § 808.1(d); *cf. Freightliner Corp. v. Myrick*, 115 S.Ct. 1483, 1487 (1995). The Lohrs' common law claims are not preempted because there are no federal "requirements" that apply to the pacemaker lead that caused Ms. Lohr's injuries. *See* Lohr Br. 39-45.

2. Medtronic's expansive view of the preemptive scope of the MDA runs directly counter to Congress' purpose of enhancing consumer protection. Under such a reading, consumers would be stripped of the protection afforded by state common law even where no federal regulatory protections have been adopted to replace them. This interpretation would leave individuals who have been injured or killed by defective medical products without any remedy, solely because of the enactment of a federal law which was supposed to enhance protections for users of medical devices. Such a result is plainly contrary to Congress' intent.

The section 510(k) process, through which the great majority of Class III medical devices (including the Medtronic Model 4011 pacemaker lead) reach the market, does not provide substantive protection to consumers against unsafe products. Rather, it guarantees consistency of treatment for equivalent medical devices. Where, as here, a device is equivalent to one that was already on the market when the MDA was enacted, the 510(k) process does nothing more than carry forward the congressional decision to "grandfather" such a pre-existing medical device —without making any inquiry into its safety.

Nor does the MDA provide any private right of action for those injured by devices entering the market through the 510(k) process. State law, therefore, provides the only means of obtaining relief for injuries or fatalities sustained because of defects in the large numbers of medical devices entering the market through this process. Under Medtronic's interpretation of the MDA, however, all consumers of medical devices would be deprived of these essential state law remedies. Such an interpretation is plainly untenable, as it would create a broad area devoid of any legal protection. *See, e.g., United Constr. Workers v. Laburnum Constr. Corp.*, 347 U.S. 656, 663-64 (1954).

ARGUMENT

I. THE MEDICAL DEVICE AMENDMENTS DO NOT PREEMPT STATE TORT LAW CLAIMS FOR INJURIES CAUSED BY A DEFECTIVE MEDICAL DEVICE

Last Term, in a unanimous decision, this Court restated the framework for analysis of preemption issues. *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S.Ct. 1671 (1995). The Court addresses claims that state laws are preempted by express preemption provisions like section 360k(a)[2] "with the starting presumption that Congress does not intend to supplant state law." *Travelers*, 115 S.Ct. at 1676 (citations omitted). "[W]here federal law is said to bar state action in fields of traditional state regulation," such as health and safety, the Court proceeds on the " 'assumption

[2] Section 521(a) of the Medical Device Amendments of 1976 is codified at 21 U.S.C. § 360k(a) and is reproduced in the appendix to the Lohrs' opening brief at pp. 1a-2a.

that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' " *Travelers*, 115 S.Ct. at 1676 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Congress did not have the clear and manifest purpose in the MDA to preempt state common law. The Lohrs' claims accordingly are not preempted.

This presumption against preemption and the corollary requirement that Congress demonstrate its preemptive purpose clearly and unambiguously are grounded on fundamental "principles of federalism." *See Department of Revenue of Oregon v. ACF Industries*, 114 S.Ct. 843, 850 (1994); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 532-33 (1992) (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part). They serve the vital "interest of avoiding unintended encroachment on the authority of the States." *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

Congress did not state clearly in the MDA any intention to preempt state common law claims. Although Congress expressly addressed the issue of preemption in section 360k, it spoke only "with generality." *See Travelers*, 115 S.Ct. at 1677. Judicial extrapolation of the general preemptive language of section 360k to preempt state common law claims would "read the presumption against pre-emption out of the law" in an area—the protection of citizens' health and safety—where state police powers are central. *See Travelers*, 115 S.Ct. at 1677. It would also violate the rule that when courts address an express preemption provision, they "must fairly but—in light of the strong presumption against preemption—nar-

rowly construe [its] precise language." *Cipollone*, 505 U.S. at 523.

Where the text of the statute does not show any "clear and manifest purpose" to preempt all state tort law liability, the Court "move[s] on" to the "structure and purpose" of the statute "as a guide to the scope of the state law that Congress understood would survive." *Travelers*, 115 S.Ct. at 1676-77. Given the structure and purpose of the MDA, section 360k(a) expresses Congress' intent to preempt only positive state law in limited circumstances. If, however, section 360k(a) is construed more broadly to encompass some aspects of state common law, the Court should defer to the FDA's determination of the appropriate accommodation of state law and federal law. *See* 21 C.F.R. § 808.1(d).

Congress did not state clearly any intent to preempt state common law claims and, therefore, it did not address the precise question of the extent of preemption. Under these circumstances, the agency's interpretation of the preemptive effect of the statute is reasonable and should be given controlling weight. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984); *see NationsBank of North Carolina, N.A. v. Variable Annuity Life Insurance Co.*, 115 S.Ct. 810, 813-14 (1995). At most, as the FDA has ruled, the MDA preempts state law only to the extent that the agency has established specific requirements applicable to particular medical devices. Here, the Lohrs' common law claims are not preempted because the FDA has not established any specific regulations applicable to the pacemaker lead that is the subject of this case.

A. The MDA Does Not Preempt State Tort Remedies

1. *Congress Did Not Have "The Clear And Manifest Purpose" To Supersede The States' Traditional Systems Of Tort Liability*

When Congress enacted the Medical Device Amendments in 1976, a substantial body of state tort law was applicable to medical devices. Claims for injuries caused by defective medical devices could be pursued under a variety of state common law doctrines, including negligence, breach of warranty, and strict liability in tort. *See, e.g.*, Edward M. Swartz, *Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments*, 18 De Paul L. Rev. 348, 358 (1969); Ann M. Caldwell, Note, *Products Liability and Medical Devices: Diagnosis and Cure*, 87 Dick. L. Rev. 779, 781-90 (1983); R.D. Hursh, Annotation, *Liability of Manufacturer or Seller For Injury Caused By Medical and Health Supplies, Appliances, and Equipment*, 79 A.L.R. 2d 401 (1961); Romualdo P. Eclavea, Annotation, *Products Liability In Connection With Prosthesis Or Other Product Designed To Be Surgically Implanted In Patient's Body*, 1 A.L.R. 4th 923, 924-25 (1980). Moreover, as Congress itself recognized, some States—most notably California—had enacted statutes and regulations governing medical devices. *See, e.g.*, Sherman Food, Drug, and Cosmetic Law, 1970 Cal. Stat. Ch. 1573, § 5, *codified at* Cal. Health & Safety Code, §§ 26600-26693, 26801-26851, *repealed by* 1995 Cal. Stat. Ch. 415, § 169; 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980); *see also* Robert S. Adler and Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924-25 & n. 131 (1994).

Although Congress explicitly addressed some aspects of the relation between the new federal statute and this preexisting body of state law in 21 U.S.C. §§ 360k and 360h(d), it did not have any intention, much less any clear and manifest purpose, to preempt state tort law. Sections 360k and 360h(d) demonstrate no intent to preempt state tort law. In section 360k, Congress spoke to the issue of preemption only at a very high level of generality, and it charged the FDA with substantial responsibility to work out the details of the accommodation of state and federal law. In section 360h(d), Congress expressly recognized that medical device manufacturers and others are subject in certain circumstances to liability under state law.

Section 360k(a), the express preemption provision of the MDA, plainly does not support any conclusion that Congress intended to preempt state tort law. In subsection (a), Congress prohibited any state "requirement" for a medical device "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device . . . ." 21 U.S.C. § 360k(a). In the following subsection, Congress narrowed the scope of preemption by authorizing the FDA to exempt certain state requirements. 21 U.S.C. § 360k(b). The statute does not define either a state "requirement" or a "requirement" under the MDA. There is simply no evidence that Congress intended a state "requirement" to include state common law tort actions. Consequently, there is no basis to conclude that Congress had "the clear and manifest purpose" to supersede the States' traditional tort laws.

Quite to the contrary, the sparse legislative history suggests that in section 360k Congress was concerned only with the appropriate accommodation of state statutes and regulations with the MDA and not with state common law. *See* 42 Fed. Reg. 30,383 (June 14, 1977). Congress focused on state and local "regulation" of medical devices and in particular on California's Sherman Food, Drug, and Cosmetic Law, which "require[d] premarket approval of all new medical devices, require[d] compliance of device manufacturers with good manufacturing practices and authorize[d] inspection of establishments which manufacture devices." H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). Although the Committee Report noted that such state "regulations" might unduly burden interstate commerce and might be preempted under subsection (a), it also stated that the "requirements imposed under the California statute serve as an example of requirements" that the FDA is authorized to exempt from preemption under subsection (b). *Id.* at 46.

Section 360h(d) also confirms that Congress did not have any "clear and manifest purpose" to preempt state common law. The FDA has power to notify the public and health professionals of unreasonable risks associated with medical devices and to order manufacturers to repair or to replace the device, to refund the purchase price, and to pay reimbursements. 21 U.S.C. §§ 360h(a), (b), (c). The statute expressly provides that compliance with these repair, replacement, refund, and reimbursement orders "shall not relieve any person from liability under Federal or State law." *Id.* § 360h(d).

In the absence of any clear and manifest congressional purpose to supersede the States' traditional

systems of tort liability, the Court should not construe the MDA to accomplish this result. *See English v. General Electric Corp.*, 496 U.S. 72, 83 (1990). Instead, the Court should hold that a state "requirement" in section 360k does not include state common law causes of action and force Congress to be politically accountable for any decision to insulate manufacturers of medical devices from tort liability. In determining the scope of preemption, and in many other contexts vital to the preservation of the federal-state balance, judicial enforcement of the rule that Congress must state clearly its intention to substantially reorder federal-state relations is a crucial means of protecting the States' role in our federal system.

2. *The Requirement That Congress Have "The Clear And Manifest Purpose" To Preempt State Law Is A Crucial Political Safeguard Of Federalism*

The Court has held repeatedly that the historic police powers of the States are not preempted "unless that was the clear and manifest purpose of Congress." *Travelers*, 115 S.Ct. at 1676 (quoting *Rice*, 331 U.S. at 230). The Court has imposed an analogous clear statement rule in many other contexts. *See Gregory v. Ashcroft*, 501 U.S. 452, 460-61 (1991). The Court, for example, requires a clear statement of congressional intent to subject the States to damages suits in state courts. *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989). Congress must make its intent to abrogate the States' Eleventh Amendment immunity "unmistakably clear in the language of the statute." *Dellmuth v. Muth*, 491 U.S. 223, 227-28 (1989) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985)). Congress must state clearly the conditions of federal grants that impose costs on the States. *Pennhurst*

State School & Hosp. v. Halderman, 451 U.S. 1, 17 (1981). Congress must also state clearly its intention to regulate the States as States. *Gregory*, 501 U.S. at 460-61, 467; *see New York v. United States*, 326 U.S. 572, 584-85 (1946) (Rutledge, J., concurring) (Congress should state "explicitly" its intention to apply a generally applicable tax to a state function).

An unambiguous expression of congressional intent to displace state law is an essential means of protecting the States' role in our federal system. *See Gregory*, 501 U.S. at 461. The requirement of a clear statement of congressional intent to alter the balance of authority between the federal government and the States permits the electorate to hold Congress accountable. Congress' political accountability is in turn the foundation of judicial deference to congressional ordering of federal-state relations.

Although *amici* have frequently argued otherwise, the Court has held that federalism limits on Congress' legislative powers are enforced primarily by the political process and not by the judicial process. *See Garcia v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528, 550-54 (1985); *but see United States v. Lopez*, 115 S.Ct. 1624 (1995). Under the Court's decisions, this judicial deference to Congress' adjustment of the balance of national and state power in our federal system is appropriate to the extent that Congress is politically accountable to the national electorate. *New York v. United States*, 505 U.S. 144, 168-69 (1992); *see Lopez*, 115 S.Ct. at 1638-39 (Kennedy, J., concurring); *id.* at 1651-52 (Souter, J., dissenting); *Federal Energy Regulatory Comm'n v. Mississippi*, 456 U.S. 742, 787 (1982) (O'Connor, J., con-

curring in the judgment in part and dissenting in part). The electorate, however, cannot hold Congress accountable unless Congress indicates, clearly and unambiguously its intent to supplant the States' authority.

This case illustrates the importance of the clear statement rule. If Congress had indicated "the clear and manifest purpose" to insulate manufacturers of replacement joints, antiwrinkle treatments, intraocular lenses, heart catheters, heart valves, pacemakers, and other medical devices from all liability under state tort law, the Medical Device Amendments of 1976 would have been subject to a very different constellation of political forces. Congress probably would have rejected the MDA if it unambiguously provided that patients injured by defective medical devices would not have any means of obtaining compensation under state law. Indeed, there would have been no possibility of enactment if, as discussed below, Congress also stated clearly that it was not creating any alternative federal provision for compensation to fill the void created by preempting state common law actions.

The question, put simply, is whether Congress, by an explicit statement, or the Court, by extrapolation of a generally worded express preemption provision, should supplant the States' traditional systems of tort liability and immunize manufacturers of defective medical devices from all state law claims for compensation. The Court should not make this decision for Congress; it should require Congress to take political responsibility for any decision to bar the States from protecting the health and safety of their citizens under their traditional systems of tort liability. In

short, in the absence of a much clearer direction from Congress, the Court should not drastically alter the federal-state balance by construing the term "requirement" in section 360k(a) to include state common law.[8] There is no support for Medtronic's argument

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[8] The requirement that Congress have a "clear and manifest purpose" to preempt state tort law is completely consistent with this Court's recent decision in *Cipollone*. In that case, six members of the Court held that the phrase "requirement or prohibition . . . imposed under State law" in an express preemption provision included both positive state enactments and state common law. 505 U.S. at 520-24 (Stevens, J., joined by Rehnquist, C.J., White and O'Connor, JJ.) and at 548-49 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part).

Nonetheless, seven members of the Court recognized that the express preemption provision must be read in the light of either the presumption against preemption or the corollary requirement that Congress must make its purpose to preempt state law "clear and manifest." Writing for the Court, Justice Stevens expressly recognized the requirement that Congress make its intention to preempt the States' historic police powers "clear and manifest." *Id.* at 516. In a separate opinion, Justice Blackmun, joined by Justices Kennedy and Souter, found that the statutory language did not embrace state common law because Congress did not "'clearly' or 'manifestly' exhibit[] an intent to preempt state common-law damages actions." *Id.* at 534. (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part). Although Justice Stevens did not directly apply this "clear and manifest purpose" rule, his plurality opinion expressly applied the presumption against preemption and concluded that state common law could be subject to preemption only in light of special factors and circumstances not present in the MDA. *Id.* at 520-24; *see* Adler and Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 923 (substantial differences between statute at issue in *Cipollone* and the MDA).

that section 360k(a) immunizes medical device manufacturers from liability under all state common law tort doctrines.

Not only does the term "requirement" in section 360k(a) fall far short of any indication that Congress had "the clear and manifest purpose" to preempt all state tort law, it is best read, in light of the structure and purpose of the MDA, as an expression of Congress' intent to preempt only state positive law. As the Lohrs argue persuasively, Congress, in section 360k(a), intended to preempt only state statutes and regulations. *See* Lohr Br. 16-34. Even if the term "requirement" in the MDA can be interpreted more expansively, however, to include some aspects of state common law, it is appropriate to defer to the agency's interpretation of section 360k(a) as a guide to the scope of state law that Congress understood would survive.

B. Even If State Tort Law Is Subject To Preemption, The FDA Correctly Limited The Scope Of Preemption

1. The FDA's Interpretation Of Section 360k(a) Is Reasonable And Entitled To Deference

The standard for judicial deference to an agency's interpretation of a statute that it administers is well-settled. If "Congress has not directly addressed the precise question at issue," courts defer to an agency's interpretation unless it is "arbitrary, capricious, or manifestly contrary to the statute." *Chevron*, 467 U.S. at 843-44. *See Hillsborough County v. Automated Medical Labs, Inc.*, 471 U.S. 707, 714-15 (1985) (Court defers to FDA determination that regulation setting standards for collection of blood plasma does not preempt state and local regulation).

As discussed above, Congress did not state clearly an intent to preempt any state common law claims; therefore, it could not have addressed the precise question whether the particular common laws claims in this case are preempted. Even if the term "requirement" in section 360k(a) could properly be read to include state common law as well as state statutes and regulations, Congress did not determine precisely the extent to which state "requirements" would be preempted by the MDA. Instead, Congress spoke to the issue of preemption only at a very high level of generality.

The FDA has taken a clear position regarding the preemptive scope of the MDA: "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . ." 21 C.F.R. § 808.1(d). In addition, the FDA has identified several types of state and local requirements that are not " 'requirements applicable to a device' within the meaning of section 521(a) of the act," and which are therefore not preempted. *Id.; see, e.g.*, 21 C.F.R. § 808.1(d)(1) (state and local requirements of general applicability are not preempted). The FDA has further elaborated on its interpretation of the MDA's preemption provision in pronouncements made in the course of rulemaking, emphasizing the need to avoid an expansive view of preemption that would undermine the congressional purpose of enhancing consumer protection. *See, e.g.*, 43 Fed. Reg. 18,661, 18,663 (May 2, 1978); 42 Fed. Reg. 30,383 (June 14, 1977).

This longstanding interpretation of the preemptive effect of section 360k(a) is reasonable and entitled to deference. The agency carefully examined the structure and the purpose of the MDA in order to determine the scope of state law that Congress intended would survive. The FDA found that Congress' purpose of protecting consumers from unsafe and ineffective medical devices would be defeated if state law was preempted before the agency could adopt "compensating" regulations under the act.[4] The agency also found that preemption of state law before issuance of specific federal regulations, which could take a considerable amount of time, would create a "regu-

[4] In promulgating its final preemption regulation, the FDA noted:

> The entire thrust of the [MDA] is to provide FDA with new and additional authority to assure that only safe and effective medical devices are permitted on the market. There is nothing in the legislative history to indicate Congress intended that the [MDA] should result in less protection for the public, which would be the natural consequence of State Controls being eliminated during the considerable period of time it will take for FDA to implement fully the new authorities provided in the [MDA].
>
> [I]nterpretations urged by the comments [that all state and local requirements were preempted as of the effective date of the MDA] would provide less public protection from unsafe and ineffective medical devices because State and local regulation of medical devices would be reduced or eliminated before compensating FDA regulations could become effective.

43 Fed. Reg. 18,661, 18,663 (May 2, 1978) (citations omitted).

latory hiatus" or a "regulatory void."[5] Recognizing that Congress intended to promote safety and to avoid any undue burden on interstate commerce, the FDA specifically found that its interpretation of section 360k(a) "will not cause an undue burden on interstate commerce because it merely allows State and local requirements to continue in effect until FDA establishes a national policy on the regulation of specific devices." 43 Fed. Reg. 18,661, 18,663 (May 2, 1978).

Although the FDA focused exclusively on the accommodation of state statutes and regulations with the MDA, its conclusions apply with equal force to accommodation of state common law with the MDA. Congress' purpose of protecting consumers from unsafe and ineffective medical devices would be defeated if the tort law incentive to manufacture safe and effective medical devices was removed by preemption

[5] The FDA noted when it proposed section 808.1(d), the preemption regulation which was subsequently adopted without change, that:

> [T]he Commissioner has narrowly construed the preemption provisions so that section 521(a) of the act [21 U.S.C. § 360k(a)] preempts State and local requirements only when a particular Federal requirement becomes applicable to a particular device by operation of the act. This avoids disruption of vital State and local programs relating to the regulation of medical devices and reduces the possibility of a regulatory hiatus that could result if State or local requirements were considered preempted prior to the time FDA implemented Federal requirements. The potential for such a regulatory void is real since it will require several years for FDA to implement fully its device regulatory programs.

42 Fed. Reg. 30,383 (June 14, 1977).

before the FDA adopted specific "compensating" regulations. There would be a "regulatory void" if the common law's indirect inducement to manufacture safe products was canceled before the FDA established any alternative safety mechanism. Moreover, until the FDA acts, the mere continuation of state tort law liability could not cause an "undue" burden on interstate commerce because "there is no greater burden . . . than if the [MDA] had not been enacted." 43 Fed. Reg. 18,661, 18,663 (May 2, 1978). Ironically, if state tort liability for a particular medical device were preempted before the FDA had promulgated specific requirements for that device, consumers would have less protection after enactment of the MDA than before.

Given these concerns, the FDA reasonably determined that section 360k(a) preempts state law "only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . ." 43 Fed. Reg. 18,661, 18,662 (May 2, 1978); 21 C.F.R. § 808.1(d). In interpreting section 360k(a), the FDA correctly recognized that the promulgation of "specific" federal law "requirements" under the MDA is the prerequisite for preemption of state law. *Cf. Freightliner Corp. v. Myrick*, 115 S.Ct. 1483, 1487 (1995).

2. *The Lohrs' Common Law Claims Are Not Preempted Because No Federal "Requirements" Apply To The Pacemaker Lead That Caused Ms. Lohr's Injuries*

Amici adopt, without repeating, the Lohrs' arguments that only device-specific federal requirements have preemptive force. *See* Lohr Br. 13-14, 39-45;

see also 21 C.F.R. § 808.1(d). Because no device-specific federal regulations apply to any of the Lohrs' claims, there can be no preemption of the state law governing those claims. *See* Lohr Br. 42-45.

* * * *

In short, the court of appeals failed to establish that Congress had "the clear and manifest purpose" to preempt state tort law, and it extended the preemptive effect of section 360k far beyond the bounds intended by Congress and beyond the bounds identified by the FDA. To the extent that the court of appeals held that the Lohrs' common law claims are preempted, its judgment is an "unintended encroachment on the authority of the States," *CSX*, 507 U.S. at 664, and should be reversed.

II. PREEMPTION OF STATE COMMON LAW DAMAGES ACTIONS WOULD LEAVE PERSONS INJURED BY MEDICAL DEVICES WITHOUT ANY MEANS OF OBTAINING COMPENSATION AND WOULD DEFEAT CONGRESS' PURPOSE OF PROTECTING CONSUMERS

Congress, spurred to action by the Dalkon Shield tragedy, enacted the MDA to protect consumers from dangerous and ineffective medical devices. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976); S. Rep. No. 33, 94th Cong., 2d Sess. 1-2, 6-7 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1070-72, 1075-76. Congress intended that consumers would be protected both by laws and regulations that prevent unsafe or ineffective medical devices from reaching the market, and by pre-existing mechanisms for compensation in the event that they are injured by a defective device. There is no evidence that Congress thought regulation alone was sufficient to protect consumers or that com-

pensation and regulation were somehow antithetical. Congress never even debated whether to deny compensation to individuals injured or killed by defective medical devices and to relegate the task of consumer protection exclusively to regulatory review and civil or criminal enforcement of regulations.

A decision by this Court construing section 360k(a) to preempt state common law tort remedies, however, would, in effect, make the decision that Congress declined to make. Preemption of state tort actions would result in a complete denial of compensation because there is no private cause of action under the MDA for damages, and it would relegate the protection of many consumers, like Ms. Lohr, exclusively to federal regulatory provisions for safety and effectiveness that have sometimes proved ineffective. *See generally Br. Am. Cur.* American Association of Retired Persons *et al.*

A. Section 510(k) Of The MDA Does Not Ensure That Medical Devices Are Safe And Does Not Establish A Private Cause Of Action For Damages Caused By A Defective Medical Device

The MDA divides medical devices into three categories on the basis of the level of risk that they create for consumers. *See* 21 U.S.C. §§ 360c(a)(1)(A)-(C); H.R. Rep. No. 853 at 34. Life-preserving devices, like pacemakers and pacemaker leads, fall into Class III, the class of medical devices involving the highest risk. 21 U.S.C. § 360c(a)(1)(C); *see* 21 C.F.R. § 860.3(c)(3). Class III devices may be subject to a pre-market approval (PMA) process requiring a determination by the FDA, on the basis of data submitted by the manufacturer, that there is "reasonable assurance" that the device is safe and effective.

21 U.S.C. § 360e(d)(2). Most Class III devices, however, have not yet been subject to the PMA process and instead come to the market under the section 510(k) process. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A); *see* S. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307 ("[O]ver 80 percent of the devices that are potentially the most dangerous (Class III), enter the market on the basis of a claim by the manufacturer that they are 'substantially equivalent' to a device already on the market.").

Under section 510(k), a manufacturer can market a Class III device if the FDA finds that it is "the 'substantial equivalent' of an already-marketed device, including a device grandfathered into the market." Medtronic Pet. App. 5a (opinion of court of appeals) (quoting 21 U.S.C. § 360e(b)(1)(B)). An FDA finding of "substantial equivalence" under section 510(k) is not a finding of safety and effectiveness. *See, e.g.*, House Comm. on Energy and Commerce, 103d Cong., 1st Sess., *Less Than The Sum Of Its Parts: Reforms Needed In The Organization, Management, And Resources Of The Food And Drug Administration's Center For Devices And Radiological Health* 8-9 (Comm. Print 1993).

Medtronic's Model 4011 pacemaker lead came to the market under the section 510(k) process as the substantial equivalent of a pre-MDA or "grandfathered" product. The FDA's decision to permit Medtronic to market its Model 4011 pacemaker lead was not a finding of safety and effectiveness. *See* Lohr Br. at 7-8. The FDA simply determined that Model 4011, like all other devices that enter the market under section 510(k), was "as safe as a predi-

cate device that itself [may be] unreasonably dangerous." *See Feldt v. Mentor Corp.*, 61 F.3d 431, 438 n.12 (5th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3534 (U.S. Jan. 26, 1996) (No. 95-1214).

Although there is no regulatory determination of the safety and effectiveness of medical devices that reach the market under the section 510(k) process, the MDA does not include any provision for compensation for those injured by these devices. There is no express private cause of action for damages under the MDA, and no federal court has ever recognized an implied private right of action under the Food, Drug, and Cosmetic Act, the statute which incorporates the MDA. *See Bailey v. Johnson*, 48 F.3d 965, 966-68 (6th Cir. 1995) (collecting cases). The Act relies exclusively on civil and criminal enforcement by the FDA, and it leaves open only a faint prospect of compensation in rare cases—a restitution order in a criminal case. *See Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29-30 (1st Cir. 1995) ("Courts in future criminal proceedings will, or should, be aware that restitution may be the only redress for those harmed by manufacturers who have failed to comply with the provisions of the MDA."), *petition for cert. filed*, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321).

In the circumstances of this case—where the FDA determined no more than that a particular medical device was the substantial equivalent of another device that was never subject to any pre-market approval and where there is no federal cause of action for damages caused by the device—preemption of state tort law remedies would deprive consumers harmed by defective devices of all means of redress. It is implausible that Congress, whose purpose was

to protect consumers, would deny consumers compensation for injuries caused by products that are simply the substantial equivalent of grandfathered products manufactured before the effective date of the MDA and that were never subject to any pre-market determination of their safety and effectiveness. *See* Adler and Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 930, 940-45. As one court recently observed,

> If safety was Congress' primary purpose, it would be strange for Congress to eliminate the safety aspects inherent in tort litigation by destroying tort litigation in the entire country with the same statute it passed to promote safety. It would be stranger still for Congress to take such dramatic action without even mentioning it as a consequence of the passage of a bill that was debated for years.

Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 211 (Ill. App. 1994) (citations omitted), *aff'd on other grounds*, 1996 Ill. LEXIS 8 (Ill. Jan. 18, 1996).

Nonetheless, Medtronic urges the Court to construe section 360k(a) to achieve this implausible and unfair result. *See* Medtronic Br. 30-46. As Medtronic notes, many courts of appeals, lower courts, and state courts have construed section 360k(a) broadly to preempt a wide array of state tort law actions. *Id.* at 37 n.19. These decisions have left consumers without any protection against defective medical devices and without any means of obtaining compensation for deaths and injuries caused by defective medical devices. In cases that would have involved similarly harsh results, however, this Court has rejected the proposition "that Congress would, without comment, remove all means of judicial recourse for those in-

jured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

B. State Law Actions Are The Only Means Of Providing Compensation For Individuals Injured By Defective Medical Devices

This case falls squarely within a line of cases holding that state common law remedies are not preempted where federal law provides no comparable or alternative remedy.[6] *E.g.*, *Silkwood*, 464 U.S. at

[6] There is an analogous doctrine that courts should not interpret federal statutes to create a regulatory void. For example, in *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983), the Court interpreted several statutory provisions explicitly allocating regulatory authority between the States and a federal regulatory agency in order to avoid creating a regulatory void and to preserve from preemption a traditional area of state regulation. The Court first found that the Atomic Energy Acts of 1946 and 1954 gave the federal government exclusive authority over radiological safety standards for commercial nuclear power plants and that Congress had left "no role . . . for the States." 461 U.S. at 206-07. After noting that Congress had not given the federal government any authority over the economic aspects of nuclear power generation, the Court, in keeping with the presumption against preemption, concluded that the States must have this type of regulatory authority because "[i]t is almost inconceivable that Congress would have left a regulatory vacuum." 461 U.S. at 207-08. *See also Mackey v. Lanier Collection Agency and Service, Inc.*, 486 U.S. 825 (1988) (preemption of one state garnishment law does not create a regulatory void because a second state garnishment law is not preempted).

The rule that state common law remedies are not preempted where federal law provides no comparable or alternative remedy is also consistent with this Court's cases finding that state laws are superseded where "the bite of pre-emption" has been eased by congressional provision of a substitute for the preempted state laws. *See Cipollone*, 505 U.S. at 541

251; *United Constr. Workers v. Laburnum Constr. Corp.*, 347 U.S. 656, 663-64 (1954); *see Cipollone*, 505 U.S. at 541-42 (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part); *cf. English*, 496 U.S. at 87-90 (federal administrative remedy does not preempt state common law action for intentional infliction of emotional distress).

For example, in *United Constr. Workers v. Laburnum Constr. Corp.*, the Court held that the Labor Management Relations Act (LMRA) did not preempt a state common law tort action for damages caused by conduct that was an unfair labor practice under the federal statute. 347 U.S. at 663-64. Although the Court had previously held that state courts could not enjoin unfair labor practices, *Garner v. Teamsters Union*, 346 U.S. 485 (1953), it refused to extend that holding to bar a state tort action. The Court explained *Garner* on the ground that Congress had provided a federal administrative remedy which was a substitute for injunctive relief. In *Laburnum*, however, the Court found that "Congress has neither provided nor suggested any substitute for the traditional state court procedure for collecting damages for injuries caused by tortious conduct." 347 U.S. at 663-64. There was no provision in the LMRA for an employer to obtain compensation for the tortious conduct of a union, and the case presented " 'an instance

(Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part); *see Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 142-45 (1990) (comprehensive federal civil enforcement scheme fills void created by preemption of state common law claim); *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54-56 (1987) (same).

of injurious conduct which the National Labor Relations Board is without express power to prevent and which therefore either is "governable by the State or it is entirely ungoverned."'" 347 U.S. at 664 (quoting *Garner*, 346 U.S. at 488) (quoting *United Auto Workers v. Wisconsin Employment Relations Bd.*, 336 U.S. 245, 254 (1949)).

Just as the Court was unwilling to find implied preemption of state common law remedies in *Laburnum*, it was unwilling in *Silkwood* to preempt a state common law tort action for punitive damages. The *Silkwood* Court recognized that Congress intended "to prohibit the States from regulating the safety aspects of nuclear development," but it found no bar to a state law action against a federally licensed nuclear plant for injuries and property damage caused by plutonium contamination. 464 U.S. at 250. Given "Congress' failure to provide any federal remedy," the Court found that "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." 464 U.S. at 251.

There is no reason why this Court should construe section 360k(a) to leave consumers of defective medical devices without any means to obtain compensation for their injuries. A narrow construction of section 360k(a) is required by the presumption against preemption and by the requirement of a clear and manifest congressional purpose to preempt state law. In this case, like *Laburnum* and *Silkwood*, there are no substitute federal private causes of action, express or implied, to fill the void if state tort law is preempted. There is no basis for believing that Congress, in enacting the MDA, intended to leave consumers without any compensation for injuries caused by

defective medical devices. It would stand the presumption against preemption on its head to insist that the States, in the exercise of their historic police powers, must overcome the inertia of the federal legislative process to secure statutory relief from the court of appeals' unduly expansive interpretation of section 360k(a). To the contrary, the burden is on Congress to make an explicit decision displacing the States' traditional systems of tort liability. Congress did not make that decision in the MDA.

CONCLUSION

The judgment of the court of appeals that the Lohrs' state law negligent design and strict liability claims are not preempted should be affirmed. The judgment that their negligent manufacture and failure to warn claims are preempted should be reversed.

Respectfully submitted,

D. BRUCE LA PIERRE
WASHINGTON UNIVERSITY
SCHOOL OF LAW
One Brookings Drive
St. Louis, MO 63130
(314) 935-6477

RICHARD RUDA *
Chief Counsel
LEE FENNELL
STATE AND LOCAL LEGAL CENTER
444 North Capitol Street, N.W.
Suite 345
Washington, D.C. 20001
(202) 434-4850

* *Counsel of Record for the* Amici Curiae

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